

Please note:

These draft proposals for revising certain sections in the current ELAP regulations were submitted to ELAP by a sub committee of the Environmental Laboratory Technical Advisory Committee. The proposals affect Definitions (Section 64801), Performance Evaluation Testing (Section 64809), and Subgroups for Fields of Testing (Section 64823).

These proposals have not yet been reviewed or evaluated by ELAP or the Department of Health Services, and do not necessarily represent the views or opinions of ELAP/ DHS.

Anyone wishing to comment on these proposals should submit their comments by June 30, 2003 to George Kulasingam, Ph.D., ELAP, 1625 Shattuck Ave, Room 101, Berkeley, CA 94709-1611. Any comments received will also be passed on to the sub committee which originated these proposals.

Article 1 Definitions

Section 64801.

- (a) Acceptance Limit – In a PT Study, the range of values around an assigned or mean value which produce an “acceptable result”.
- (b) "Alternate Test Procedure" means an analytical test method, or procedure that is different in technique from an approved method but detects and quantifies to the same degree of precision, accuracy, and level of detection.
- (c) “Analyte” means a substance that has some public health importance that can occur in the materials regulated by the Safe Drinking Water Act, (SDWA), Clean Water Act (CWA), Federal Insecticide, Fungicide, Rodenticide, Act (FIFRA), Toxic Substances Control Act (TSCA), Resource Conservation and Recovery Act (RCRA), Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or “Superfund” Act), Safe Food & Drug Act and corresponding State Acts.
- (d) Approved Method – Analytical test method or procedure that has been approved by either Federal or State regulatory authorities under appropriate statutes for the analysis of a particular combination of matrix and analyte.
- (e) Assigned Value – In a PT study, the value which corresponds to the amount

prepared and verified as the actual amount present in the PT sample.

- (f) "Auxiliary laboratory facility" means any stationary place which:
 - (1) is operated by the owner of a laboratory for the purpose of providing additional capacity, or to reduce or eliminate sample contamination;
 - (2) and performs analyses in one or more of the same Field(s) of Testing as the laboratory to which it is auxiliary; and
 - (3) is under the supervision of the same Laboratory Director as the laboratory which it is auxiliary; and
 - (4) only receives samples from, and reports raw analytical data to, the laboratory to which it is auxiliary for its generation of the final report; and
 - (5) is located such that the transport of samples to the auxiliary laboratory does not affect the quality of the analytical results.
- (g) "A Complete Application" means a verified application for certification containing all the information required in section 64805(a) or (b).
- (h) "Contact Person" means an individual designated by the Laboratory Director to act as a contact between the laboratory and the Department for purposes of exchanging information between the Department and the laboratory.
- (i) "Facility or Facilities" means fixed or portable building(s), which contain the analytical and ancillary operating equipment, supplies and space necessary to perform the analyses in the Field(s) of Testing for which a laboratory is certified, and includes storage areas.
- (j) "Field of Testing (FOT)" means a group of approved methods or analytical instruments with similar target analytes as defined in the Health and Safety Code 100860.1(a).
- (k) "Laboratory" shall have the same meaning as given in Health and Safety Code section 100825(a)
- (l) "Laboratory Director" means the person who, for the laboratory and its auxiliary or mobile laboratories, if any, is in charge of all analytical and operational laboratory activities; supervises all personnel, including those designated as Principal Analysts; and is the person responsible for the quality of reported data.
- (m) "Matrix" means the type of material that is regulated by the acts listed in (b).

- (n) Mean Value – In a PT Study, the value, calculated using all of the individual results of participating laboratories for each analyte using established statistics techniques.
- (o) “Method” means an analytical procedure listed in statute, permit, or directive by a State authority responsible for the enforcement of the acts listed in (b).
- (p) “Mobile Laboratory” means a vehicle, vessel, aircraft, or trailer, and is operated by the same owner as a certified stationary laboratory, and which is designed and equipped for the purpose of transporting and using laboratory equipment to perform analyses in one of the Fields of Testing for which the stationary laboratory is certified.
- (q) “National Environmental Laboratory Accreditation Conference (NELAC)” is a voluntary association of State and federal officials formed to adopt a uniform set of environmental laboratory accreditation criteria and procedures. NELAC adopts and publishes Standards that are voluntarily used by state agencies to accredit environmental laboratories.
- (r) “Owner” means any person who is a sole proprietor of a laboratory, or any person who holds a partnership interest in a laboratory, or any person who is an officer, or 5% (five percent) or more shareholder in a corporation which owns a laboratory.
- (s) “Owner's Agent” or “Agents of Owners” means those persons who have been designated by the Owner(s) of the laboratory to act in its behalf for purposes of complying with these regulations or the statutes under which these regulations are adopted.
- (t) “Proficiency Testing (PT)” is a procedure for evaluating a laboratory’s performance under controlled conditions relative to a given set of criteria through analysis of samples containing analytes with concentrations unknown to the laboratory, provided by an external source which prepared the sample and knows the concentration.
- (u) “PT sample” means a sample containing a known concentration of one or more analytes accredited by ELAP, in a matrix matching those defined in Article 12, used to evaluate the analytical performance of a laboratory. The concentration is known by the PT provider but not by the laboratory during analysis.

- (v) "PT study" means each lot of PT samples prepared and distributed. A PT sample study shall be made available to accredited laboratories for a discrete amount of time, from the "opening" date until the "closing" date.
- (w) "Principal Analyst" means a person who either supervises the activities of others in, or conducts, the analyses of environmental samples using sophisticated laboratory instruments. For these purposes, "sophisticated laboratory instruments" means: gas chromatograph/mass spectrometers (GC/MS), inductively coupled plasma spectrometers (ICP), inductively coupled plasma-mass spectrometers (ICP-MS), liquid chromatograph/mass spectrometers (LC-MS), atomic absorption spectrophotometers (AA), gas chromatographs (GC), alpha particle or gamma ray spectrophotometer, electron microscopes (EM), polarized light microscope (PLM), or high pressure liquid chromatographs (HPLC).
- (x) "Stationary Laboratory" means a laboratory that is permanent and non-movable and may include fixed-in-place vehicles.
- (y) "Trade Secrets" means any information that meets the definition in Section 6254.7(d) of the Government Code.
- (z) "Trailer" means a vehicle designed for carrying persons or property on its own structure and for being drawn by a motor vehicle and so constructed that no part of its weight rests upon any other vehicle. This definition is the same as the definition given in Section 630, Vehicle Code.
- (aa) "Utility-owned" means laboratories owned and operated by federal, state, city, or county agencies.
- (bb) "Vehicle" means a device by which any person or property may be propelled, moved, or drawn upon a highway, excepting a device moved exclusively by human power or used exclusively upon stationary rails or track. This definition is the same as the definition as given in Section 670, Vehicle Code.
- (cc) "Verified Application" means that the truth and accuracy of the information in the application has been attested to by the signature of a laboratory Owner.
- (dd) "Vessel" included ships of all kinds, steamboats, steamships, canal boats, barges, sailing vessels, and every structure adapted to be navigated from place to place for the transportation of merchandise or persons. This definition is the same as given in Section 21, Harbors and Navigation Code.